METHOD FOR MAPPING ELECTRICAL ACTIVITY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application No. 10/430,512, filed May 6, 2003, entitled METHOD FOR MAPPING ELECTRICAL ACTIVITY, which is a continuation of U.S. Patent Application No. 09/551,467, filed April 17, 2000, which claims the benefit of U.S. Provisional Application No. 60/178,478, filed January 27, 2000, the entire disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to an improved mapping catheter that is particularly useful for mapping electrical activity in a tubular region of or near the heart.

BACKGROUND OF THE INVENTION

Atrial fibrillation is a common sustained cardiac arrhythmia and a major cause of stroke. This condition is perpetuated by reentrant wavelets propagating in an abnormal atrial-tissue substrate. Various approaches have been developed to interrupt wavelets, including surgical or catheter-mediated atriotomy. Prior to treating the condition, one has to first determine the location of the wavelets. Various techniques have been proposed for making such a determination. None of the proposed techniques, however, provide for measurement of the activity within a pulmonary vein, coronary sinus or other tubular structure about the inner circumference of the structure.

SUMMARY OF THE INVENTION

The present invention is directed to a method for measuring electrical activity within a tubular region of or near the heart, e.g., a pulmonary vein, the coronary sinus, the superior vena cava, or the pulmonary outflow tract. The method involves using a catheter with a mapping assembly that has a generally circular region with one or more spaced-apart electrodes mounted thereon. The mapping assembly is positioned within the tubular region so that the electrodes are in contact with an inner generally circumferential surface inside the tubular structure.

In one embodiment, the invention is directed to a method for mapping electrical activity within a tubular region of or near the heart having an inner circumference. The method comprises inserting into the heart a distal end of a catheter comprising an elongated tubular catheter body having an outer wall, proximal and distal ends, and at least one lumen extending therethrough. The catheter further includes a mapping assembly comprising a tubular structure having a continuous generally circular main region generally transverse and distal to the catheter body and having an outer circumference. The tubular structure has at least one electrode carried by the generally circular main region of the mapping assembly. The outer circumference of the generally circular main region is contacted with the inner circumference of the tubular region. The electrical activity of the tubular region is mapped with the at least one electrode along the generally circular main region.

In another embodiment, the invention is directed to a method for mapping electrical activity within a tubular region of or near the heart having an inner circumference. The method comprises inserting into the heart a distal end of a catheter comprising an elongated tubular catheter body having an outer wall, proximal and distal ends, and at least one lumen extending therethrough. The catheter further includes a mapping assembly at the distal end of the catheter body. The mapping assembly comprises a plurality of electrodes arranged about a continuous circumference of the mapping assembly. The continuous circumference of the mapping assembly is contacted with the inner circumference of the tubular region, and the electrical activity within the tubular region is mapped with the plurality of electrodes.

In yet another embodiment, the invention is directed to a method for mapping electrical activity within a tubular region of or near the heart having an inner circumference comprising inserting into the heart a distal end of a catheter. The catheter comprises an elongated tubular catheter body having an outer wall, proximal and distal ends, and at least one lumen extending therethrough, and a mapping assembly at the distal end of the catheter body. The mapping assembly comprises a plurality of electrodes arranged about a curved region of the mapping assembly. The curved region consists of a single continuous generally circular curve and has an outer surface. The outer surface of the curved region of the mapping assembly is contacted with the inner circumference of the tubular region, and the electrical activity within the tubular region is mapped with the plurality of electrodes.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side cross-sectional view of an embodiment of the catheter of the invention;

FIG. 2 is a side cross-sectional view of a catheter body according to the invention, including the junction between the catheter body and intermediate section;

FIG. 3 is a cross-sectional view of the intermediate section, including the junction between the intermediate section and the mapping assembly;

FIG. 4 is a schematic perspective view of the mapping assembly according to the invention;

FIG. 5 is a side view of the mapping assembly of the invention in a clockwise formation;

FIG. 6 is a side view of the mapping assembly according to the invention in a counterclockwise formation rotated 90° relative to the assembly depicted in FIG. 5;

FIG. 7 is a schematic view of the mapping assembly according to the invention; and

FIG. 8 is a schematic view of the mapping assembly according to the invention depicting the relationship between the first and last electrodes.

DETAILED DESCRIPTION

In a particularly preferred embodiment of the invention, there is provided a catheter having a mapping assembly at its distal end. As shown in FIG 1, the catheter comprises an elongated catheter body **12** having proximal and distal ends, a intermediate section **14** at the distal end of the catheter body, a control handle **16** at the proximal end of the catheter body, and a mapping assembly **17** mounted at the distal end of the catheter to the intermediate section.

With reference to FIG. 2, the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **18**. The catheter body **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **20** made of polyurethane or PEBAX. The outer wall **20** comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter

body **12** so that, when the control handle **16** is rotated, the intermediate section **14** of the catheter **10** will rotate in a corresponding manner.

The outer diameter of the catheter body **12** is not critical, but is preferably no more than about 8 french, more preferably 7 french. Likewise the thickness of the outer wall **20** is not critical, but is thin enough so that the central lumen **18** can accommodate a puller wire, lead wires, and any other desired wires, cables or tubes. If desired, the inner surface of the outer wall **20** is lined with a stiffening tube (not shown) to provide improved torsional stability. A particularly preferred catheter has an outer wall **20** with an outer diameter of from about 0.090 inch to about 0.94 inch and an inner diameter of from about 0.061 inch to about 0.065 inch.

The intermediate section **14** comprises a short section of tubing **22** having three lumens. The first lumen **30** electrode carries lead wires **50**, the second lumen **32** carries a puller wire **64**, and the third lumen **34** carries a support member **24**. The tubing **22** is made of a suitable non-toxic material that is preferably more flexible than the catheter body **12**. A presently preferred material for the tubing **22** is braided polyurethane, i.e., polyurethane with an embedded mesh of braided stainless steel or the like. The size of each lumen is not critical, but is sufficient to house the lead wires, puller wire or support member.

The useful length of the catheter, i.e., that portion that can be inserted into the body excluding the mapping assembly **17**, can vary as desired. Preferably the useful length ranges from about 110 cm to about 120 cm. The length of the intermediate section **14** is a relatively small portion of the useful length, and preferably ranges from about 3.5 cm to about 10 cm, more preferably6 from about 5 cm to about 6.5 cm.

A preferred means for attaching the catheter body **12** to the intermediate section **14** is illustrated in FIG. 2. The proximal end of the intermediate section **14** comprises an outer circumferential notch **26** that receives the inner surface of the outer wall **22** of the catheter body **12**. The intermediate section **14** and catheter body **12** are attached by glue or the like.

If desired, a spacer (not shown) can be located within the catheter body between the distal end of the stiffening tube (if provided) and the proximal end of the intermediate section. The spacer provides a transition in flexibility at the junction of the catheter body and intermediate section, which allows this junction to bend smoothly without folding or kinking. A catheter having such a spacer is described in U.S. Patent No. 5,964,757, the disclosure of which is incorporated herein by reference.

At the distal end of the intermediate section **14** is a mapping assembly, as shown in FIGs. 3 to 7. The mapping assembly is formed from the distal end of the support member **24** covered by a non-conductive covering **28**. The mapping assembly comprises a generally straight

proximal region **38**, a generally circular main region **39** and a generally straight distal region **40**. The proximal region **38** is mounted on the intermediate section **14**, as described in more detail below, so that its axis is generally parallel to the axis of the intermediate section. The proximal region **38** preferably has an exposed length, e.g., not contained within the intermediate section **14**, ranging from about 3 mm to about 12 mm, more preferably about 3 mm to about 8 mm, still more preferably about 5 mm inch, but can vary as desired.

The generally circular main region **39** does not form a flat circle, but is very slightly helical, as shown in FIGs.4 to 6. The main region **39** has an outer diameter preferably ranging to about 10 mm to about 25 mm, more preferably about 12 mm to about 20 mm, still more preferably about 15 mm. The transition region **41** of the straight proximal region **38** and generally circular main region **39** is slightly curved and formed such that, when viewed from the side with the proximal region at the top of the circular main region as shown in FIG. 5, the proximal region (along with the intermediate section **14**) forms an angle α with the curved region ranging from about 75° to about 95°, preferably from about 83° to about 93°, more preferably about 87°. The main region **39** can curve in a clockwise direction, as shown in FIG. 5, or a counterclockwise direction, as shown in FIG. 6. When the assembly **17** is turned 90°, as shown in FIG. 6, so that the transition region **41** is near the center of the main region, the proximal region (along with the intermediate section **14**) forms an angle β with the main region ranging from about 90° to about 135°, preferably from about 100° to about 110°, more preferably about 105°.

The support member **24** is made of a material having shape-memory, i.e., that can be straightened or bent out of its original shape upon exertion of a force and is capable of substantially returning to its original shape upon removal of the force. A particularly preferred material for the support member **24** is a nickel/titanium alloy. Such alloys typically comprise about 55% nickel and 45% titanium, but may comprise from about 54% to about 57% nickel with the balance being titanium. A preferred nickel/titanium alloy is nitinol, which has excellent shape memory, together with ductility, strength, corrosion resistance, electrical resistivity and temperature stability. The non-conductive covering **28** can be made of any suitable material, and is preferably made of a biocompatible plastic such as polyurethane or PEBAX

A series of ring electrodes **36** are mounted on the non-conductive covering **28** of the generally circular main region **39** of the mapping assembly **17**. The ring electrodes **36** can be made of any suitable solid conductive material, such as platinum or gold, preferably a combination of platinum and iridium, and mounted onto the non-conductive covering **28** with glue or the like. Alternatively, the ring electrodes can be formed by coating the non-conductive

covering **28** with an electrically conducting material, like platinum, gold and/or iridium. The coating can be applied using sputtering, ion beam deposition or an equivalent technique.

In a preferred embodiment, each ring electrode **36** is mounted by first forming a hole in the non-conductive covering **28**. An electrode lead wire **50** is fed through the hole, and the ring electrode **36** is welded in place over the lead wire and non-conductive covering **28**. The lead wires **50** extend between the non-conductive covering **28** and the support member **24**. The proximal end of each lead wire **50** is electrically connected to a suitable connector **37**, which is connected to a source of RF energy (not shown).

The number of ring electrodes **36** on the assembly can vary as desired. Preferably the number of ring electrodes ranges from about six to about twenty, preferably from about eight to about twelve. In a particularly preferred embodiment, the assembly carries ten ring electrodes. The ring electrodes **36** are preferably approximately evenly spaced around the generally circular main region **39**, as best shown in FIG. 7. In a particularly preferred embodiment, a distance of approximately 5 mm is provided between the centers of the ring electrodes **36**.

FIGs. 7 and 8 show a particularly preferred electrode arrangement. As explained above, the generally circular main region **39** is very slightly helical, although FIGS. 7 and 8 depict the main region as a flat circle, as it would generally appear when viewed from the distal end of the catheter. The generally straight distal region **40** forms a tangent relative to the generally circular main region **39** and contacts the main region at a tangent point **43**. A first electrode **36a** is provided, which is the electrode that is on the generally circular main region **39** closest to the proximal region **38**. A second electrode **36b** is provided, which is the electrode that is on the generally circular main region **39** closest to the distal region **40**. Preferably, the first electrode **36a** is positioned along the circumference of the generally circular main region **39** at a distance θ of no more than about 55° from the tangent point, more preferably no more than about 48° from the tangent point, still more preferably from about 15° to about 36° from the tangent point. Preferably the second electrode **36b** is positioned along the circumference of the generally circular main region **39** at a distance ω of no more than about 55° degrees from the tangent point, more preferably no more than about 48° from the tangent point, still more preferably from about 15° to about 36° from the tangent point. Preferably the first electrode **36a** is positioned along the circumference of the generally circular main region **39** at a distance γ of no more than 100° from the second electrode **36b**, preferably no more than 80° from the second electrode, still more preferably from about 30° to about 75° from the second electrode.

If desired, additional electrodes (not shown) could be mounted along the intermediate section **14**, the generally straight proximal section **39**, the transition region **41**, and generally straight distal region **40**.

The generally straight distal region **40** is provided with an atraumatic design to prevent the distal end of the mapping assembly **17** from penetrating tissue. In the depicted embodiment, the distal region **40** comprises a tightly wound coil spring **44** made, for example, of stainless steel, such as the mini guidewire commercially available from Cordis Corporation (Miami, Florida) or a coil having a 0.0045 inch wire size and a 0.009 inch inner diameter, such as that commercially available from Microspring. The coil spring **44** is mounted at its proximal end in a short piece of tubing **45** with polyurethane glue or the like, which is then glued or otherwise anchored within the non-conductive covering **28**. The tubing **45** is less flexible than the non-conductive covering **28** but more flexible than that support member **24** to provide a transition in flexibility along the length of the mapping assembly **17**. The distal end of the distal region **40** is capped, preferably with polyurethane glue **46**, to prevent body fluids from entering the mapping assembly **17**. In the depicted embodiment, the generally straight distal region **40** has a length of about 0.5 inch, but can be any desired length, for example, ranging from about 0.25 inch to about 1.0 inch. The generally straight distal region **40** is preferably sufficiently long to serve as an anchor for introducing the catheter into a guiding sheath, as discussed in more detail below, because the mapping assembly **17** must be straightened upon introduction into the sheath. Without having the generally straight distal region **40** as an anchor, the mapping assembly **17** has a tendency to pull out of the guiding sheath upon its introduction into the guiding sheath. Additionally, if desired, the distal region **40** can be formed, at least in part, of a radiopaque material to aid in the positioning of the mapping assembly **17** under fluoroscopy.

The junction of the intermediate section **14** and mapping assembly **17** is shown in FIG. 3. The non-conductive covering **28** is attached to the tubing **22** of the intermediate section by glue or the like. The support member **24** extends from the third lumen **32** into the non-conductive covering **28**. The proximal end of the support member **24** terminates a short distance within the third lumen **32**, approximately about 5 mm, so as not to adversely affect the ability of the intermediate section **14** to deflect. However, if desired, the proximal end of the support member **24** can extend into the catheter body **12**.

The lead wires **50** attached to the ring electrodes **36** extend through the first lumen **30** of the intermediate section **14**, through the central lumen **18** of the catheter body **12**, and the control handle **16**, and terminate at their proximal end in the connector **37**. The portion of the lead wires **50** extending through the central lumen **18** of the catheter body **12**, control handle **16**

and proximal end of the intermediate section **14** are enclosed within a protective sheath **62**, which can be made of any suitable material, preferably polyimide. The protective sheath **62** is anchored at its distal end to the proximal end of the intermediate section **14** by gluing it in the first lumen **30** with polyurethane glue or the like.

The puller wire **64** is provided for deflection of the intermediate section **14**. The puller wire **64** extends through the catheter body **12**, is anchored at its proximal end to the control handle **16**, and is anchored at its distal end to the intermediate section **14**. The puller wire **64** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire **64**. The puller wire **64** preferably has a diameter ranging from about 0.006 to about 0.010 inch.

A compression coil **66** is situated within the catheter body **12** in surrounding relation to the puller wire **64**. The compression coil **66** extends from the proximal end of the catheter body **12** to the proximal end of the intermediate section **14**. The compression coil **66** is made of any suitable metal, preferably stainless steel. The compression coil **66** is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil **66** is preferably slightly larger than the diameter of the puller wire **64**. The Teflon® coating on the puller wire **64** allows it to slide freely within the compression coil **66**. The outer surface of the compression coil **66** is covered by a flexible, non-conductive sheath **68**, e.g., made of polyimide tubing.

The compression coil **66** is anchored at its proximal end to the outer wall **20** of the catheter body **12** by proximal glue joint **70** and at its distal end to the intermediate section **14** by distal glue joint **72**. Both glue joints **70** and **72** preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the outer surface of the catheter body **12** and the central lumen **18**. Such a hole may be formed, for example, by a needle or the like that punctures the outer wall **20** of the catheter body **12** which is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil **66** and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil.

The puller wire **64** extends into the second lumen **32** of the intermediate section **14**. Preferably the puller wire **64** is anchored at its distal end to the distal end of the intermediate section **14**, as shown in FIG. 3. Specifically, a T-shaped anchor is formed, which comprises a short piece of tubular stainless steel **80**, e.g., hypodermic stock, which is fitted over the distal end of the puller wire **64** and crimped to fixedly secure it to the puller wire. The distal end of the tubular stainless steel **80** is fixedly attached, e.g., by welding, to a cross-piece **82** formed of

stainless steel ribbon or the like. The cross-piece **82** sits beyond the distal end of the second lumen **32**. The cross-piece **82** is larger than the lumen opening and, therefore, cannot be pulled through the opening. The distal end of the second lumen **32** is then filled with glue or the like, preferably a polyurethane glue. Within the second lumen **32** of the intermediate section **14**, the puller wire **64** extends through a plastic, preferably Teflon®, puller wire sheath (not shown), which prevents the puller wire **64** from cutting into the wall of the intermediate section **14** when the intermediate section is deflected.

Longitudinal movement of the puller wire **42** relative to the catheter body **12**, which results in deflection of the intermediate section **14**, is accomplished by suitable manipulation of the control handle **16**. Examples of suitable control handles for use in the present invention are disclosed, for example, in U.S. Patent Nos. Re 34,502 and 5,897,529, the entire disclosures of which are incorporated herein by reference.

In use, a suitable guiding sheath is inserted into the patient with its distal end positioned at a desired mapping location. An example of a suitable guiding sheath for use in connection with the present invention is the Preface™ Braiding Guiding Sheath, commercially available from Cordis Webster (Diamond Bar, California). The distal end of the sheath is guided into one of the atria. A catheter in accordance with the present invention is fed through the guiding sheath until its distal end extends out of the distal end of the guiding sheath. As the catheter is fed through the guiding sheath, the mapping assembly **17** is straightened to fit through the sheath. Once the distal end of the catheter is positioned at the desired mapping location, the guiding sheath is pulled proximally, allowing the deflectable intermediate section **14** and mapping assembly **17** to extend outside the sheath, and the mapping assembly **17** returns to its original shape due to the shape-memory of the support member **24**. The mapping assembly **17** is then inserted into a pulmonary vein or other tubular region (such as the coronary sinus, superior vena cava, or inferior vena cava) so that the outer circumference of the generally circular main region **39** of the assembly is in contact with a circumference inside the tubular region. Preferably at least about 50%, more preferably at least about 70%, and still more preferably at least about 80% of the circumference of the generally circular main region is in contact with a circumference inside the tubular region.

The circular arrangement of the electrodes **36** permits measurement of the electrical activity at that circumference of the tubular structure so that ectopic beats between the electrodes can be identified. The size of the generally circular main region **39** permits measurement of electrical activity along a diameter of a pulmonary vein or other tubular structure of or near the heart because the circular main region has a diameter generally corresponding to that of a

pulmonary vein or the coronary sinus. Additionally, because the main region **39** preferably does not form a flat circle, but instead is somewhat helical, as shown in FIG. 4, it is easier for the user to guide the mapping assembly **17** into a tubular region.

If desired, two or more puller wires can be provided to enhance the ability to manipulate the intermediate section. In such an embodiment, a second puller wire and a surrounding second compression coil extend through the catheter body and into an additional off-axis lumen in the intermediate section. The first puller wire is preferably anchored proximal to the anchor location of the second puller wire. Suitable designs of catheters having two or more puller wires, including suitable control handles for such embodiments, are described, for example, in U.S. Patent Application Serial Nos. 08/924,611, filed September 5, 1997; 09/130,359, filed August 7, 1998; 09/143,426, filed August 28, 1998; and 09/157,055, filed September 18, 1998, the disclosures of which are incorporated herein by reference.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fairest scope.